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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/187,385	11/06/98	MARKOVIC	S 07039/119001

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HM22/0508

EXAMINER

HOLLERAN, A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED:

05/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/187,385

Applicant(s)

Markovic, S.N.

Examiner

Anne Holleran

Art Unit

1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 20, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 18-26 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 is/are allowed.
- 6) ☒ Claim(s) 1-8 and 18-25 is/are rejected.
- 7) ☒ Claim(s) 9-12 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Art Unit: 1642

### **DETAILED ACTION**

1. This communication is responsive to the amendment filed February 20, 2001.

Claims 15 and 16 were canceled.

Claims 1-12 and 18-26 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections Withdrawn:***

3. The rejection of claims 1-2, 15, 16, and 18-26 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims and upon further consideration.

4. The rejection of claims 15 and 16 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claimed invention is withdrawn in view of the cancellation of claims 15 and 16.

Art Unit: 1642

Because Ucar discloses three commercial preparations of alpha-interferon, Ucar discloses articles of manufacture which are the same as that claimed.

8. The rejection of claims 1-8 and 18-22 under 35 U.S.C. 103(a) as being unpatentable over Markovic et al [a] (Markovic, S.N. et al., Int. J Cancer, 45: 788-794, 1990; IDS ref. "CH") in view of either Golub et al (Golub, S.H. et al., J. Nat. Cancer Inst., 68: 703-710, 1982; IDS ref. "AO"), Toliou et al (Toliou, Th. Et al. Eur. Urol, 29: 252-256, 1996; IDS ref. "DH") or Neeffe et al (Neeffe, J.R. et al., Cancer Res. 45: 874-878, 1985) is maintained for the reasons of record.

Applicant's arguments have been carefully considered but are unpersuasive. Applicant's arguments do not appear to be different from the arguments presented previously. Applicant's attention is drawn to the Table 2 of Golub which shows using alpha interferon within the dose range claimed, and to Neeffe (page 874, 2nd column) which directs one to use dosages of  $0.9 \times 10^6$  U/m<sup>2</sup> after higher doses were found to be toxic.

9. The rejection of claim 23 under 35 U.S.C. 103(a) as being unpatentable over Markovic et al [b] (Markovic, S.N. et al., Clinical Immunology and Immunopathology, 60: 181-189, 1991; IDS Ref. "CF") in view of either Golub (supra), Toliou (supra) or Neeffe (supra) is maintained for the reasons of record.

Applicant's arguments have been carefully considered but are unpersuasive. Applicant's arguments do not appear to be different from the arguments presented previously.

Art Unit: 1642

10. The rejection of claims 1-6 and 18-25 under 35 U.S.C. 103(a) as being unpatentable over Lennard et al (Lennard, T.W. et al., Br. J. Surgery, 72(10): 771-776, 1985) is maintained for the reasons of record.

Applicant's arguments have been carefully considered but are unpersuasive. Applicant argues that Lennard does not teach or suggest any dosage of alpha interferon and asserts that the prior art teaches one to use high dosages of alpha interferon (cites Kirkwood et al). This is not persuasive because the Kirkwood paper is not directed to a study of the use of alpha interferon as an immunostimulatory agent. Furthermore, the prior art does provide teachings of using alpha interferon at dosages that are within the ranges recited in the claims (see Golub and Neefe, discussed above).

### ***Conclusion***

Claims 1-8 and 18-25 are rejected. Claims 9-12 are objected to for depending from a rejected claim. Claim 26 is free of the art and is allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1642

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892.

Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

AH

Anne L. Holleran  
Patent Examiner  
May 4, 2001

AC  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600



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1	A...	1
2	CLM	1
3	REM	4

Total number of pages: 6

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